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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,085	01/12/2001	Jaap Goudsmit	9250-28CT	3169
20792	7590	12/19/2001		
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
			EXAMINER TUNG, JOYCE	
			ART UNIT 1656	PAPER NUMBER 8

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/760,085**

Applicant(s)  
**Goudsmit et al.**

Examiner  
**Joyce Tung**

Art Unit  
**1656**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 6, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-37 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/125,241.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1656.

#### ***Information Disclosure Statement***

1. The reference 9 lined through in PTO-1449 filed 3/16/2001 has been considered, but it does not constitute a publication under USPTO guidelines. It is suggested to delete reference 9.

#### ***Specification***

2. The use of the trademark Triton X-100 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 16-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 32-37 are vague and indefinite because it is unclear how the language “amplification motif” in claim 32 is defined in the specification.

b. Claims 16-31 are vague and indefinite because of the language “a mixture of both” in claim 16. It is not clear what is meant by the language. Does it mean that the mixture contains both of single stranded and double stranded nucleic acid sequence. It is suggested to clarify uncertainty.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 16-21, 25-26, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al. (WO 95/04140).

Boom et al. disclose a process for isolating nucleic acid from a nucleic acid-containing starting material (See the Abstract). This suggests that the material contains either a double stranded nucleic acid or a single stranded nucleic acid or a mixture of a double stranded nucleic acid and single stranded nucleic acid. The protocol B is suitable for isolating dsDNA from complex starting materials (See pg. 14, lines 13-31) in which 900 ul GEDTA (GEDTA is meant a solution of 120g GuSCN (Guanidine thiocyanate) in 100ml 0.2M EDTA pH=8) (as recited in claim 21) and 40ul silica particles is used (See pg. 14, lines 13-15). The supernatant contains the purified double stranded DNA (See pg. 14, lines 30-31). The protocol Y is for simultaneous purification of dsDNA, ssDNA and single or double stranded RNA comprises using buffer L6 and silica beads (See pg. 15, lines 2-6). The buffer L6 contains 120g GuSCN in 22 ml 0.2 M EDTA pH 8 (See pg. 12, lines 30-34). The pellet is obtained by centrifugation, then nucleic acid is eluted and the supernatant containing nucleic acid is obtained from centrifugation (See pg. 15, lines 15-22). The size of the silica particle is from 63-200  $\mu$ M (See pg. 10, lines 30-31).

Boom et al. do not disclose using the second liquid composition for purifying a single stranded nucleic acid as claimed. However, Boom et al. do disclose that the protocol is used for isolating single stranded nucleic acid sequence (See pg. 15, lines 1-22).

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One of ordinary skill in the art at the time of the instant invention would have been motivated to apply a second time isolation of a single nucleic acid from the supernatant containing single stranded nucleic acid with a reasonable expectation of success because repeating purification steps for a reasonable expectation of success is a routine practice for purification in the art. In fact, the protocol Y of Boom is used for isolating a single stranded nucleic acid (See pg. 15, lines 1-22). Further more, the method of Boom et al. is used in complex starting materials and in a unprecedentedly rapid, simple and reproducible manner with a low risk of contamination (See pg.2, lines 26-33 and pg. 3, lines 1-9). It would have been prima facie obvious to carry out the method as claimed.

7. Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al (5,043,272) in view of Mullis et al. (4,965,188) and Sambrook et al. (Molecular cloning, second edition, pg. 8.11-8.17).

Hartley et al. disclose using an oligonucleotide with a random sequence for amplification (See column 5, lines 10-14). The macromolecular entities contain nucleic acid including double-stranded DNA, single-stranded DNA or mRNA and the RNA can be converted to DNA by reaction with reverse transcriptase (See column 3, lines 22-33). The amplification may be performed without prior knowledge of specific sequences (See the abstract). Sequence amplified can be further evaluated, detected or sequenced (See column 8, lines 60-68 to column 9, lines 1-4).

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Hartley et al. do not disclose using a primer which is labeled and RNase H to obtain the single stranded nucleic acid from RNA/DNA hybrid.

Sambrook et al. disclose that avian reverse transcriptase has RNase H activity (See pg. 8.11).

Mullis et al. disclose a method of amplification in which a labeled primer is used (See column 5, lines 3-7) and mRNA is reverse transcribed into cDNA and the cDNA is amplified (See column 34, lines 34-65).

One of ordinary skill in the art would have been motivated to combine the references of Hartley et al., Sambrook et al. and Mullis et al. make the instant invention with a reasonable expectation of success because the method of Hartley et al. can be performed without prior knowledge of specific sequences in which the target nucleic acid may be DNA or RNA and the primer contains a random nucleic acid sequence.(See the abstract), the method of Mullis et al. is for amplifying a desired nucleic acid sequence in which DNA or RNA is may be single- or double-stranded (See column 1, lines 28-33) and Sambrook et al. indicate an enzyme which has RNase H activity which is used for reverse transcription. It would have been prima facie obvious to combine these references for carrying out the method as claimed.

***Allowable Subject Matter***

7. Claims 22-24 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if rewritten to overcome the rejection(s) under 35

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U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Sequence Rules***

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth as follows

All nucleic acid sequence in the specification are required to have SEQ ID NO, for example, the nucleic acid sequences on pg. 13 in the specification.

**APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).**

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.




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10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

December 12, 2001

  
**ETHAN C. WHISENANT**  
**PRIMARY EXAMINER**